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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,353	05/09/2005	Jong-Soo Woo	Q87237	4817

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,353	WOO ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9 May 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

Applicant's election without traverse of Group I, claims 1-10, in the reply filed on 11 January 2008 is acknowledged.

Claims 11-13 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 January 2008.

The remaining claims 1-10 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statements filed 9 May 2005 are acknowledged and have been reviewed.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Objections

Claim 4 is objected to because of the following informalities: a value of "l" is reflected for the number of weight parts of paclitaxel. Given the remainder of the language in the claim, the Examiner interprets this value to be "1". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 contains the trademark/trade name Eudragit. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a hydrophilic polymer and, accordingly, the identification/description is indefinite.

The recitation "in the solution as a solvent-free basis" in claim 5 is not clear because it is not clear which solution the claim refers to: prior to or after dissolution in the organic solvent.

The phrase "capable" recited twice in claim 6, renders the claim indefinite because it is not clear whether dissolution of the additives or paclitaxel is part of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nair (EP 0521675) in view of Patel et al. (U.S. Patent 6,248,363) and STN*Easy* search for paclitaxel.

The instant claims are directed to a method employing a supercritical fluid process comprising dissolving a preparation of paclitaxel and an additive in a mixed organic solvent, mixing the formed solution with a supercritical fluid by spraying to form the particles, removing the organic solvent by washing the particles with supercritical fluid and recover the particles. Claim 2 further limits the additive to a surfactant or hydrophilic polymer and claim 3 further limits hydrophilic polymer to specific compounds such as hydroxypropyl methylcellulose (HPMC). Claim 4 recites a ratio of hydrophilic polymer to paclitaxel ranging from 0.1 to 20 parts polymer to 1 part paclitaxel. Claim 5 recites a limitation to the polymer of claim 2 such that it is present in the solution in the range of 1-75% (w/w). Claim 6 further limits the mixed

organic solvent to being a preparation of a paclitaxel-dissolving solvent and a hydrophilic polymer-dissolving solvent. Claim 7 recites a ratio range for the solvent mixture of claim 6. Claims 8 and 9 recite specific compounds limiting the two different solvents of claim 6. Claim 10 recites temperature and pressure ranges to the method of claim 1.

Nair teaches a method for extracting taxol from a mixture containing taxol comprising the step of contacting the mixture with a supercritical fluid which is capable of solubilizing at least part of the contained taxol (claims 1-3). Paclitaxel is also known by the name taxol (see STN*Easy* search results). Claims 9 teaches that the supercritical fluid includes in admixture with each other or a modifier compounds such as a haloalkane. Chloroform is a haloalkane that is taught (pg. 3, lines 28-31). Claims 10 and 11 teach that the modifier, admixed with supercritical carbon dioxide, is an organic solvent. Methanol, ethanol, and isopropanol are also taught as organic solvents (pg. 3, lines 28-31). Claim 15 teaches that the pressure of the supercritical fluid employed is greater than 72.9 atmospheres, which is equivalent to 73.9 bar. Claims 17 and 18 teach that the temperature of the supercritical fluid employed is greater than 31.3°C and more specifically from about 35-45°C. Claims 19 and 20 teach separating the supercritical fluid containing the taxol from the remaining mixture into a separate depressurized chamber.

Nair does not teach that the taxol is mixed with a surfactant or hydrophilic polymer and thus also does not teach the ratios or ranges associated with the hydrophilic polymer or surfactant. The organic solvent is not expressly taught as being mixed with the taxol mixture prior to contacting the supercritical fluid nor are the ratios of the organic solvents taught.

Patel et al. teach the preparation of solid pharmaceutical compositions which have encapsulation coats prepared from lipophilic surfactants (col. 4, lines 4-12). Paclitaxel is taught

as a preferred active ingredient (col. 7, lines 31-40). Additives such as polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC) and hydroxyl propyl cellulose (HPC) are taught (col. 39, lines 31-37) as well as dichloromethane (col. 40, lines 36-37). Patel also teaches that several methods by which the solid compositions may be prepared by dispersion in a supercritical fluid may be used (col. 48, lines 55-61).

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to include with the mixture containing taxol as taught by Nair, additives such as HPMC, HPC, PVP or Eudragit when using a method for solid dispersion comprising a supercritical fluid process with a reasonable expectation of successfully obtaining the desired extracted nanoencapsulated, solidly-dispersed particles. Patel et al. teach that it may be desirable to employ water soluble polymers such as HPMC or Eudragit, particularly for taste masking applications (col. 42, lines 28-32). Therefore, modification of a paclitaxel formulation to apply the hydrophilic polymer (e.g. hydroxypropyl methylcellulose) prior to contacting it with a supercritical fluid, as earlier described, is well within the purview of the skilled artisan.

Furthermore, it is *prima facie* obvious to alter the order of addition of the aforementioned components such as including the organic solvent with the supercritical fluid rather than dissolving the taxol mixture within the organic solvent first, with the result being that of the solid dispersion composition of Applicant's instant claims 1-10. The basis for this *prima facie* obviousness rejection can be found in the following case law: *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), wherein selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; and *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), wherein selection of any order of mixing ingredients is *prima facie*

obvious.

Neither reference teaches the ratio of the hydrophilic polymer to paclitaxel, the percent by weight of the hydrophilic polymer in composition or the ratio of the components of the organic solvent as claimed by the Applicants. Since the values of each parameter with respect to the claimed method is adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal percentage of hydrophilic polymer (relative to the amount of paclitaxel to be added) to add to the formulation as well as the optimal ratio for the organic solvent mixture in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these ingredient amounts would have been obvious at the time of Applicant's invention.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615